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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,110	11/21/2003	Kilian Waldemar Conde-Frieboes	6568.200-US	1807

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NOVO NORDISK, INC.  
PATENT DEPARTMENT  
100 COLLEGE ROAD WEST  
PRINCETON, NJ 08540

EXAMINER
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TUCKER, ZACHARY C

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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08/16/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nnipatent@novonordisk.com

## Office Action Summary

Application No.

10/719,110

Applicant(s)

CONDE-FRIEBOES ET AL.

Examiner

Zachary C. Tucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/21/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 22Jan04, 23Aug04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

***Requirement for Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42, drawn to piperazinedione compounds of Formula (I), classified in class/subclasses 544/365, 370, 372, 376, 385.
- II. Claims 43-62 drawn to various methods wherein the piperazinedione compounds as set forth in Group I are employed, classified in class/subclasses 514/253.13, 254.01, 254.05, 255.02.

The inventions are independent or distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, a method of modulating melanocortin activity can be practiced with a product which is materially different from those characterized by Group I as set forth herein. The *method step* of modulating melanocortin activity, as claimed in Group II claims, is practicable with a materially different product. Melanocortin receptors are known from the prior art. For example WO 02/059107 (Backer et al) discloses melanocortin receptor agonists, and is prior art with respect to the instant application.

For the purposes of a Requirement for Restriction between a product and process of using the product, claims drawn to a method of using the product are not construed such that (because those process claims incorporate limitations of the product in the practice of the process) the process as claimed could *not* be practiced with another product, simply

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because the process (being restricted) recites that the product is employed in its practice. Arguments along these lines, in a request for reconsideration of this Requirement, will not be persuasive. The logic underlying arguments such as these is *petitio principii* "reasoning," or "circular reasoning." The Office has a long-established policy for Restriction between a product and a process for using the product. Clearly, the argument wherein it is alleged that there could be no means for practicing the process for using a product with a materially different product, because the product itself is recited in the method would render any and all Restriction between product and process for using a product improper.

The methods which are set forth in Group II furthermore will present different non-prior art issues in the examination. The determination of whether or not the methods according to those claims meet the requirements of the first paragraph of 35 U.S.C. 112 will be considerably more involved than the enablement determination for the Group I compounds. A survey of the medical literature, from before the invention was made, up to and including the time that the invention was made, is necessary. This survey of the medical literature will focus on agents which have similar pharmacological activity to the compounds of the present invention, as opposed to similar structure. Only the activity is of interest in the determination of the state of the art with respect to the therapeutic application of agonists of the MC4 receptor (which is the activity possessed by the compounds of the present invention). Thus, the two Groups will present different non-prior art issues in the examination of their respective subject matters.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### ***Specification***

The specification is objected to because at the end of the written description of the invention, a lengthy section headed "Exemplary Aspects of the Invention" is printed. This section, basically, consists of 274 claims describing the invention. This extra section of claims must be deleted in its entirety. Patent claims may not be in the specification.

#### ***Information Disclosure Statements***

Signed, initialed and dated forms PTO-1449, which accompanied the Information Disclosure Statements filed by applicants on 22 January 2004 and 23 August 2004, are enclosed herewith. The examiner has reviewed those submissions.

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***Conclusion***

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'ZC Tucker', with a long horizontal line extending to the right.

ZACHARY C. TUCKER  
PRIMARY EXAMINER